



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

PATENT APPLICATION

Inventors: Barry N. Gardiner  
Paul T. McDonald  
Richard D. Phipps

SC/Serial No.: 08/781,579

Filed: January 9, 1997

Title: SUTURED STAPLE SURGICAL FASTENERS,  
INSTRUMENTS AND METHODS FOR  
MINIMALLY INVASIVE VASCULAR  
AND ENDOSCOPIC SURGERY

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS  
37 C.F.R. §1.9(f) AND §1.27(b) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R. §1.9(c) for purposes of paying reduced fees under §41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention identified by the above TITLE and INVENTORS, and described in:

☐ the Specification filed herewith  
☒ the Application having the above SC/Serial No. and Filed date  
Patent No. \_\_\_\_\_ issued \_\_\_\_\_

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 C.F.R. §1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 C.F.R. §1.9(d) or a nonprofit organization under 37 C.F.R. §1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☒ No such person, concern, or organization.  
☐ Persons, concerns or organizations listed below.

\* Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. §1.27)

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NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

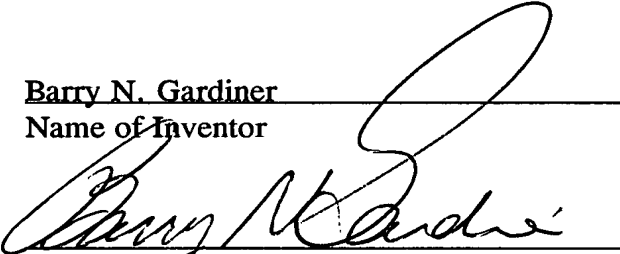
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small business entity is no longer appropriate. (37 C.F.R. §1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Barry N. Gardiner

Name of Inventor



Signature of Inventor

Date:

4/4/97

Paul T. McDonald

Name of Inventor



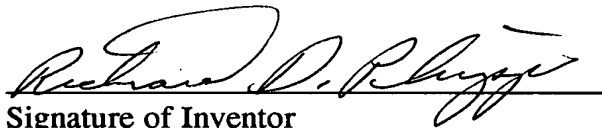
Signature of Inventor

Date:

4/4/97

Richard D. Phipps

Name of Inventor



Signature of Inventor

Date:

4-18-97

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### **Title 37, Code of Federal Regulations, §1.9(c-f)**

(c) An **independent inventor** as used in this chapter means any inventor who (1) has not assigned, granted, conveyed, or licensed, and (2) is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not likewise be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section.

(d) A **small business concern** as used in this chapter means any business concern as defined by the Small Business Administration in 13 CFR 121.12. For the convenience of the users of these regulations, that definition states:

**121.12 Small business for paying reduced patent fees.** (a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41 (a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit

*organization under this section. For the purpose of this section concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.*

(e) A **nonprofit organization** as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e) (2) or (3) of this section if it were located in this country.

(f) A **small entity** as used in this chapter means an **independent inventor**, a **small business concern** or a **nonprofit organization**.

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In re Application ) PATENT APPLICATION  
)  
Inventors: Barry N. Gardiner )  
Paul T. McDonald )  
Richard D. Phipps )  
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SC/Serial No.: Unknown )  
)  
Filed: Herewith )  
)  
Title: SUTURED STAPLE SURGICAL )  
FASTENERS, INSTRUMENTS AND )  
METHODS FOR MINIMALLY )  
INVASIVE VASCULAR AND )  
ENDOSCOPIC SURGERY )  
\_\_\_\_\_ )

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am the original, first and sole inventor (if one name is listed below), first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SUTURED STAPLE SURGICAL FASTENERS, INSTRUMENTS  
AND METHODS FOR MINIMALLY INVASIVE  
VASCULAR AND ENDOSCOPIC SURGERY

the specification of which (check applicable ones):

  X   is filed herewith;  
\_\_\_\_\_ was filed with the above-identified "Filed" date and "SC/Serial No."  
\_\_\_\_\_ was amended on (or amended through) \_\_\_\_.

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I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose information which is material to the examination of the application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

(1) Full name of first

1-00 joint inventor: Barry N. Gardiner, M.D.

(1) Residence: 13 Charles Hill Road, Orinda, California 94563 CA

(1) Post Office Address: Same as above

(1) Citizenship: U.S.A.

(1) Inventor's signature: *Barry N. Gardiner*

(1) Date: 1/7/97

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2-00

(2) Full name of second

joint inventor: Paul T. McDonald, M.D.

(2) Residence: 13337 Campus Drive, Oakland, California 94619

CA

(2) Post Office Address: Same as above

(2) Citizenship: U.S.A.

(2) Inventor's signature: Paul T. McDonald

(2) Date: 6 JAN 97

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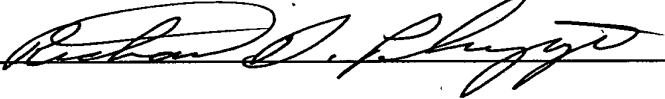
3-00

(3) Full name of third  
joint inventor: Richard D. Phipps

(3) Residence: 790 La Crosse Drive, Morgan Hill, California 95037 CA

(3) Post Office Address: Same as above

(3) Citizenship: U.S.A.

(3) Inventor's signature: 

(3) Date: 1-2-97

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Title 37, Code of Federal Regulations, §1.56

**SECTION 1.56. DUTY TO DISCLOSE INFORMATION  
MATERIAL TO PATENTABILITY**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98.\* However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office; or

(ii) Asserting an argument of patentability.

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

\* §§1.97(b)-(d) and 1.98 relate to the timing and manner in which information is to be submitted to the Office.

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AND ENDOSCOPIC SURGERY

POWER OF ATTORNEY BY INVENTORS UNDER 37 C.F.R. §1.34(b)

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

As a named Inventor in the above-identified patent application, I hereby appoint Brian I. Marcus, Reg. No. 34,511, an attorney of FLIESLER, DUBB, MEYER & LOVEJOY LLP, to prosecute this application and transact all business in the United States Patent & Trademark Office connected therewith.

Please direct all telephone calls to Brian I. Marcus, (415) 362-3800.

Please address all correspondence to:

Brian I. Marcus, Esq.  
FLIESLER, DUBB, MEYER & LOVEJOY LLP  
Four Embarcadero Center, Suite 400  
San Francisco, California 94111-4156

Barry N. Gardiner  
Name of Inventor

Signature of Inventor

Date:

Paul T. McDonald  
Name of Inventor

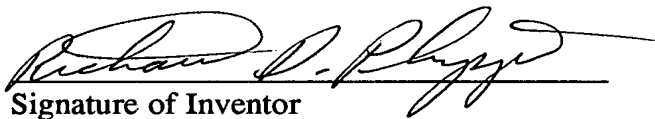
Signature of Inventor

Date:

08781579-010997

Richard D. Phipps

Name of Inventor



Signature of Inventor

Date: 4-18-97

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